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Docket No.: 043956-0159

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of

L.A. Johnson

Patent No.: 5,135,759

Issue Date: August 4, 1992

For: METHOD TO PRESELECT THE SEX OF OFFSPRING

**REQUEST FOR WITHDRAWAL OF INTERIM EXTENSION OF PATENT TERM
WITHOUT PREJUDICE**

Mail Stop Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On August 11, 2009, the U.S.P.T.O granted an interim patent term extension which extends the term of U.S. Patent No. 5,135,759 (the '759 patent) for a period of one year from the original patent term expiration date, i.e., until August 4, 2010. Exhibit A. However, as a result of further research, patent owner now appreciates that the actual expiration date of the '759 patent is April 26, 2011. Specifically, since the '759 patent was filed on April 26, 1991 and issued on August 4, 1992, under the Uruguay Rounds Agreements Act (URAA; Public Law 103-465), it is entitled to a patent term that is the longer of 17 years from the date of issuance or 20 years from the date of first filing i.e., April 26, 2010. Accordingly, it is respectfully requested that, subject to acceptance of the predicate for this request, the interim patent term extension granted in the above-referenced patent be withdrawn without prejudice and subject to reinstatement as of the actual, i.e., transitional term, expiration date.

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FACTS AND APPLICABLE LAW

The '759 was filed April 26, 1991 and issued August 4, 1992. The '759 patent relates to methods for the separation, by flow sorting, of intact, viable X and Y chromosome-bearing sperm populations based on relative DNA content; surgical insemination of the sorted sperm into females; and the subsequent birth of sexed offspring with a phenotypic sex ratio consistent with predictions based on the relative DNA content of the sorted sperm populations. The claimed methods are the subject of a New Drug Application (NDA) pending before the U.S. Food and Drug Administration (FDA).

Enacted in 1994 in order to harmonize international patent rights, the Uruguay Rounds Agreements Act (URAA; Public Law 103-465) amended 35 U.S.C. §154 to provide a patent term for all patents in force or filed as of June 8, 1995, of the longer of 17 years from the date the patent was granted or 20 years from the date of the first filing of the patent application. All patents that are filed after June 8, 1995 have a patent expiration date of 20 years from the date of first filing of the patent application.

For patents, such as the '759 patent, that matured from applications filed prior to June 8, 1995 and prosecuted to issuance in less than three years, the URAA provides an extension of patent term, that is the difference between 17 years from issuance and 20 years from filing. The difference is often referred to as the 'delta period.'¹

Congress included a limitation in amended 35 U.S.C. § 154 to protect businesses that have could not have anticipated the extension of a competitor's patent through the delta period.² During the delta period, a patentee has limited remedies vis-à-vis such protected competitors.

¹ *DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 35 U.S.P.Q.2D (BNA) 1718 (Fed. Cir. 1995).

² 35 U.S.C. 154 Contents and term of patent; provisional rights.

(c) CONTINUATION.-

(1) DETERMINATION-The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) REMEDIES-The remedies of sections 283, 284, and 285 of this title shall not apply to acts which -

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(continued...)

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In 1984 Congress passed the Drug Price Competition and Patent Restoration Act, *i.e.*, Hatch-Waxman Act, which added Section 156 to the Patent Act permitting patent term extension for patents on products (or processes for making or using the same) that are human drug products, medical devices, food additives, and color additives subject to regulation under the Federal Food, Drug and Cosmetic Act. The Act restores a portion of the patent term during which the patentee is unable to sell or market a product while awaiting government approval, such as the Food and Drug Administration's (FDA) review of a prescription drug. Regardless of the time so lost, the restoration period is limited to no more than five years and the effective patent term including the restoration period may not exceed 14 years following FDA approval of the new drug.³

In *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996), the U.S. Court of Appeals for the Federal Circuit delineated the combined effects of the URAA and the Hatch-Waxman Act for patents issued prior to June 8, 1995. The appellate court stated that all,

pre-June 8, 1995, patents are entitled to add on the restoration extension to a 20-year from filing term regardless of when such extension is granted except for those patents kept in force on June 8, 1995, only because of a restoration extension. Under this interpretation, all provisions of both URAA and Hatch-Waxman can reasonably be given effect. *Merck & Co. v. Kessler*, 80 F.3d 1543 at 1550.

The court further summarized the relationship of differing rights between the pre-URAA patent term and the post-URAA patent term (delta period):

For pre- June 8, 1995, patents, a patentee would have full exclusionary rights for 17 years, followed by rights only to equitable remuneration (neither lost profits, an injunction, punitive damages, nor attorney fees) with respect to a certain class of infringers for the period from the end of the 17-year term to the end of the new 20-year term (the delta period), followed by entitlement to full exclusionary rights but only

(3) REMUNERATION.-The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

³ Effective patent term is the period of time spanning FDA approval and patent term expiration.

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with respect to the approved product during the period of the restoration extension. *Id.*, 80 F.3d 1543 at 1551

In summary, for an FDA-extended pre-June 8, 1995 issued patent such as the '759 patent, the court envisaged three potential phases of patent protection: 1) the 17-year term with full exclusionary rights, 2) a transitional rights period with limited remedies extending to 20-years post filing, *i.e.*, the delta period; and finally 3) another period of full exclusionary rights resulting from an FDA extension. Thus, the scope of exclusionary rights for the '759 varies as follows:

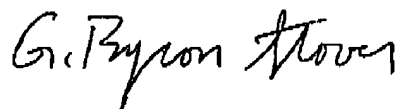
- 1) August 4, 1992 to August 4, 2009: Full exclusionary rights
- 2) August 5, 2009 to April 26, 2011: Transition rights ('delta period')
- 3) April 27, 2011 to April 27, 2016 (max): Full exclusionary rights

Period 3) above represents the maximum five-year extension available under the Hatch-Waxman Act, which includes interim patent term extension. The '759 patent claims that read on the product for which FDA approval is being sought are eligible for the entire five years extension beginning April 27, 2011.

Per Exhibit A, an interim extension under 35 U.S.C. § 156(d)(5) extending the term of the '759 patent for a period of one year from the original statutory expiration date, *i.e.*, August 4, 2010, was granted by the U.S.P.T.O. and published in the Federal Register on August 4, 2009. In the order granting interim extension, the Acting Director of the U.S.P.T.O. stated that the patent owner's application for request had been timely filed. Notwithstanding, the holding of *Merck & Co. v. Kessler* requires that an application for interim extension, which under 35 U.S.C. § 156(d)(5) must be filed during the period beginning six months prior to expiration of the patent and ending three weeks prior to expiration of the patent, is due, during the period beginning October 26, 2010 and ending April 5, 2011. As such, it now appears the application for interim patent term extension was prematurely filed *i.e.*, consistent with the original statutory term but premature with respect to the expiration of the transitional term. Accordingly, the patent owner requests withdrawal of the interim extension without prejudice, subject to it being refilled within 6 months of the expiration of the delta period, *i.e.*, within the period 6 months prior to April 26, 2011.

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Respectfully submitted,



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